UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/339,922	06/24/1999	WILLIAM D. HUSE	P-IX-3536	3233

23601 7590 04/16/2002

CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	20

DATE MAILED: 04/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/339,912	Applicant(s) HUXE ET AL
	Examiner GAMBEL	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 1/8/02

2a)☑ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-45

4a) Of the above claim(s) _____ is/are withdrawn from consideration. 21-24

5)☑ Claim(s) _____ is/are allowed. 34-45

6)☑ Claim(s) _____ is/are rejected. 1-20, 25-33

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's amendment, filed 1/8/02 (Paper No. 18), has been entered.
Claims 1, 3, 4, 6, 7, 9, 10, 12, 25, 27 and 29-33 have been amended.
Claims 34-45 have been added.

Claims 1-20 and 25-45 are under consideration.

Claims 21-24 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.
This Office Action will be in response to applicant's arguments, filed 1/8/02 (Paper No. 18).
The rejections of record can be found in the previous Office Action (Paper No. 16).

3. Upon reconsideration of applicant's arguments, filed 1/8/02 (Paper No. 18) in conjunction with the disclosure on pages 15-16 of the specification with respect to "functional fragments", the previous rejection under 35 U.S.C. 112, first paragraph, enablement, has been withdrawn.

4. Claims 3, 6, 9, 12, 13 and 33 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention essentially for the reasons of record set forth in Paper No. 15.

Applicant is reminded that this is a written description rejection rather than an enablement rejection under 35 U.S.C. 112, first paragraph.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submit that there specification provides sufficient description and guidance to convey to one skilled in the art that the inventors were in possession of the claimed invention at the time the invention was made. Applicant asserts that there are sufficient structural and functional characteristics in the claims. Applicant asserts that the claims do not rely upon a single CDR but comprise a particular CDR and functional characteristics and/or "having" certain SEQ ID NOS. .

The instant claims are drawn to antibodies and nucleic acid molecules encoding said antibodies wherein the claims recited the following limitations:
"substantially the same" LM609 grafted antibodies;
LM609 grafted antibodies which comprise one particular "CDR" selected from a Markush
and/or nucleic acids encoding said antibodies; and
"having the sequence".

Such antibodies and nucleic acid molecules encoding said antibodies do not meet the written description provision of 35 USC 112, first paragraph.

There is insufficient guidance and direction as to the written description of these antibodies which are substantially the same as another LM609 grafted antibody; these antibodies which rely upon a single "CDR" encompassed by the claimed products.

It is noted that "having the sequence" is considered open language, which would indicate that the sequences set forth in claim 33 comprise sequences both 3' and 5', including non-coding and coding sequences.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides (proteins) and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481, 1483. In Fiddes v. Baird, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.
Thus, the specification fails to describe these DNA sequences. The Court further elaborated that generic statements are not an adequate written description of the genus because it does not distinguish the claimed genus from others, except by function. Finally, the Court indicated that while applicants are not required to disclose every species encompassed within a genus, the description of a genus is achieved by the recitation of a representative number of DNA molecules, defined by nucleotide sequence, falling within the scope of the genus, See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

"Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

Therefore, there is insufficient written description for the "claimed limitations indicated above" other than a clear recitation of LM609 grafted antibodies and nucleic acids which encode said antibodies; which, in turn, rely upon a clear structure and $\alpha v\beta 3$ specificity under the written description provision of 35 USC 112, first paragraph.

Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001

Applicant's arguments are not found persuasive.

5. Claims 1-20 and 25-33: It is apparent that the LM609 antibody is required to practice the claimed invention. As a required element, it must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell line / hybridoma which produces this antibody. See 37 CFR 1.801-1.809.

Given the disclosure (e.g. see column 15, paragraph 2) and the claims (e.g. see claims 3 and 16) encompassing the instant LM609 antibody produced by the hybridoma designated ATCC HB 9537 set forth in U.S. Patent No. 5,753,230 (1449); the conditions for the deposit of biological materials under 35 USC 112, first paragraph, with respect to LM609 have been satisfied.

Applicant's amendment, filed 1/8/02 (Paper No. 18), relies upon the recitation of SEQ ID NOS. For the variable domains of both the heavy and light chains of LM609.

However, it is noted that the sequence of an entire immunoglobulin satisfies the biological deposit of said immunoglobulin. Note that satisfaction for the biological deposit of the specific LM609 antibody requires the disclosure and recitation of its entire amino acid sequence and not based upon partial sequences.

Applicant's arguments are not found persuasive.

6. Claims 1-20 and 25-33 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-20 and 25-33 are indefinite in the recitation of "LM609" because its characteristics are not known. The use of "LM609" grafted antibody antibodies as the sole means of identifying the claimed antibody / antibodies renders the claims indefinite because "LM609" is merely a laboratory designation which does not clearly define the claimed product(s), since different laboratories may use the same laboratory designations to define completely distinct cell lines .

Given that the LM609 is the referenced antibody in the claimed invention, applicant is invited to clarify the metes and bounds of LM609 in the context of the claimed invention.

Applicant's amendment, filed 1/8/02 (Paper No. 18), relies upon the recitation of SEQ ID NOS. For the variable domains of both the heavy and light chains of LM609.

However, in addition to the deposit issues above with respect to the LM609 antibody, partial sequences do not clearly identify the identifying characteristics of the LM609 antibody.

Applicant's arguments are not found persuasive.

B) Claims 1-20 are indefinite in the recitation of "enhanced LM609 grafted antibody" because the term "enhanced" is a relative term which renders the claims indefinite. The term "enhanced" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree and/or parameter(s) of "enhanced" is encompassed by the claimed invention, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 15.

Applicant relies upon pages 16-17 of the instant specification such that "enhanced" means that a functional characteristic(s) has been altered or augmented compared to a references antibody so that the antibody exhibits a desirable property or activity.

However, as pointed out previously, the claims do not define which functional or structural characteristic(s) that is enhanced. Again, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant's arguments are not found persuasive.

C) Claims 3, 6, 9, 12 are indefinite in the recitation of "substantially the same" because the phrase "substantially the same" is a relative phrase which renders the claims indefinite. The phrase "substantially the same" is is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree and/or parameter(s) of "substantially the same" is encompassed by the claimed invention, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record set forth in Paper No. 15.

Applicant submits that the "substantially the same" references to a sequence that shows a considerable degree, amount or extend of sequence identity when compared to a reference sequence, as set forth on pages 13-15 of the instant specification.

However, as pointed out previously, the claims do not define which structural characteristic(s) that are substantially the same. Again, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant's arguments are not found persuasive

D) Applicant should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06

7. Claims 3, 6, 9 and 10 are rejected under 35 U.S.C. § 102(a) as being anticipated by Huse et al. (WO 98/33919; 144) (see entire document) essentially for the reasons of record.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that the Huse et al. does not teach the claimed antibodies and encoding nucleic acids, particularly antibodies having a CDR selected from SEQ ID NOS: 104, 106 and 110.

However, given the recitation of "substantially the same sequence"; the prior art humanized LM609 antibodies and fragments thereof taught by Huse et al. encompass the limitations of the claimed invention. Huse et al. teach that the selection of such LM609 antibodies is based upon their specificity and inhibitory properties for $\alpha v\beta 3$; including modified and high affinity antibodies; which, in turn, are useful for diagnosis and therapy.

Again, it appears that the instant SEQ ID NOS: 33, 34, 89, 90, 101, 102, 107, 108, 109, 110, 111 and 112 are disclosed in WO 98/33919.

The instant claims do not require the recitation of SEQ ID NOS: 104, 106 and 110. The claimed recitation of "substantially the same sequence" which reads on various sequences based upon the native LM609 antibody which is the reference antibody both in the instant invention and in the prior art.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced humanized LM609 antibodies, fragments thereof and nucleic acids encoding said antibodies.

Applicant's arguments are not found persuasive.

8. Claim 1-20 and 25-33 are rejected under 35 U.S.C. § 102(b) as being anticipated by Wu et al. (PNAS 95: 6037-6042, 1998; 1449) (see entire document) essentially for the reasons of record set forth in Paper No. 15.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that the Huse et al. does not teach the claimed antibodies and encoding nucleic acids, particularly antibodies having a CDR selected from SEQ ID NOS: 104, 106 and 110.

However, given the recitation of "substantially the same sequence"; the prior art humanized LM609 antibodies and fragments thereof taught by Wu et al. encompass the limitations of the claimed invention. Wu et al. teach the stepwise in vitro affinity maturation of the αvβ3-specific humanized LM609 antibody; including the improved affinity of the antigen binding fragments of said LM609 variants as well as the construction of the CDR and combinatorial libraries and the screening of phage expression libraries for said LM609 variants.

The instant claims do not require the recitation of SEQ ID NOS: 104, 106 and 110. The claimed recitation of "substantially the same sequence" which reads on various sequences based upon the native LM609 antibody which is the reference antibody both in the instant invention and in the prior art.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antibody variants and libraries comprising said antibody variants.

It is noted that the comparison of the instant products with prior art is difficult since the Office is not equipped to manufacture the claimed product and/or prior art products that appear to be same or nearly the same and conduct comparisons. The burden is on the applicant to establish a patentable distinction between the claimed and referenced LM609 variants and libraries comprising the nucleic acids encoding said LM609 variants. See In re Best, 195 USPQ 430, 433 (CCPA 1977); In re Marosi, 218 USPQ 289, 292-293 (Fed. Cir. 1983); In re Fitzgerald et al., 205 USPQ 594 (CCPA 1980).

Applicant's arguments are not found persuasive.

9. Claims 3, 6, 9, 12 are rejected under 35 U.S.C. § 102(e) as being anticipated by Brooks et al. (U.S. Patent No. 5,753,230; 1449) (see entire document) for the reasons of record set forth in Paper No. 15.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that the Brooks et al. does not teach the claimed antibodies and encoding nucleic acids, particularly antibodies having a CDR selected from SEQ ID NOS: 104, 106 and 110.

However, given the recitation of "substantially the same sequence"; the prior art humanized LM609 antibodies and fragments thereof as well as nucleic acids encoding said antibodies and fragments taught by Brooks et al. encompass the limitations of the claimed invention. Brooks et al. teach the LM609 antibody, including humanized LM609 antibodies (columns 15-18 and claims such as claim 12-13 and 30-31).

The instant claims do not require the recitation of SEQ ID NOS: 104, 106 and 110. The claimed recitation of "substantially the same sequence" which reads on various sequences based upon the native LM609 antibody which is the reference antibody both in the instant invention and in the prior art.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antibody variants and libraries comprising said antibody variants.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the referenced antibody variants and libraries comprising said antibody variants.

10. Claims 3, 6, 9 and 12 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Brooks et al. (U.S. Patent No. 5,753,230; 1449) OR Wu et al. (PNAS 95: 6037-6042, 1998; 1449) in view of art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, as disclosed on pages 8-39 or Examples I and II of the instant specification or as cited by references on the 1449 essentially for the reasons of record set forth in Paper No. 15.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that the Wu et al. and Brooks et al. do not teach the claimed antibodies, particularly antibodies having a CDR selected from SEQ ID NOS: 104, 106 and 110.

However, given the recitation of "substantially the same sequence"; the prior art humanized LM609 antibodies and fragments thereof taught by Wu et al. and/or Brooks et al. would have been expected properties of the prior art LM609-specific antibodies encompassed by the claimed limitations.

Again, the instant claims do not require the recitation of SEQ ID NOS: 104, 106 and 110. The claimed recitation of "substantially the same sequence" which reads on various sequences based upon the native LM609 antibody which is the reference antibody both in the instant invention and in the prior art.

Brooks et al. teach the LM609 antibody as well as humanized forms of this antibody and claim methods of using the LM609 antibody as well as humanized forms of this antibody (see entire document, particularly columns 15-19 and the claims).

Wu et al. teach the stepwise in vitro affinity maturation of the αvβ3-specific humanized LM609 antibody; including the improve affinity of the antigen binding fragments of said LM609 variants as well as the construction of the CDR and combinatorial libraries and the screening of phage expression libraries for said LM609 variants (see entire document, including Abstract, Materials and Methods, Results and Discussion).

The art known gene cloning and expression strategies for deriving recombinant antibodies and fragments thereof, are disclosed on pages 8-39 or Examples I and II of the instant specification or cited by references on the 1449 are of record.

With respect to enhanced LM609-specific antibodies and nucleic acids encoding said antibodies; given the teachings of humanized LM609 antibodies and art known methods to generate such humanized antibodies which retain the desired functional characteristics of the native antibody and to alter said antibody for therapeutic uses, including human therapy, as taught and known in the prior art.

Furthermore as pointed out above, Wu et al. teach that affinity maturation leads to the increased affinity of αvβ3-specific humanized LM609 antibody variants (see entire document).

As pointed out previously; the amino acid and nucleic acid sequences associated with the LM609 antibody including those of humanized LM609 antibodies and antibody variants with increased affinity for αvβ3 would have been available to the ordinary artisan, given the availability of the LM609 antibody and hybridoma together with general immunoglobulin gene cloning and expression strategies, including the affinity maturation schemes as taught by Wu et al.. It would have been have been a matter of routine experimentation well within the ordinary skill level of art to generate humanized LM609 antibodies and antibody variants thereof, DNA encoding said antibodies. Given the highly conserved nature of immunoglobulin gene organization and structure and the availability of probes and PCR primers for immunoglobulin gene cloning, one of ordinary skill in the art could have isolated the functionally rearranged heavy and light chain variable regions from the LM609 hybridoma cell line and determined their sequences with a complete expectation of success. For example, the ordinary artisan does not need to determine the amino acid sequences of a rearranged V (variable) region before cloning. The claims do not differ unexpectedly or unobviously from what one of ordinary skill in the art would have expected to obtain given the known LM609 hybridoma thereof, the known heavy and light chain and the art known techniques regarding the production of humanized antibody and antibody variants selected for higher affinity, as acknowledged by the number of available art known procedures disclosed in the instant specification and cited on the Information Disclosure Statement. .

In addition, Wu et al. teach the construction and availability of the CDR and combinatorial libraries and the screening of phage expression libraries for LM609 variants (see entire document, including Materials and Methods).

From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's arguments are not found persuasive.

11. Claims 3, 6, 9 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the pending claims of copending application USSNs 08/791,391 and 08/790,540. It appears that the instant claims and the pending claims are drawn to the same or similar LM609 antibody and variants thereof, including those that read on instant SEQ ID NOS: 33, 34, 89, 90, 101, 102, 107, 108, 111, 112

This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that the copending applications do not recite the claimed antibodies, particularly antibodies having a CDR selected from SEQ ID NOS: 104, 106 and 110.

However, given the recitation of "substantially the same sequence"; the prior art humanized LM609 antibodies and fragments thereof claimed in USSNs 08/790,540 and 08/791,3981 would have been expected properties of the prior art LM609-specific antibodies encompassed by the claimed limitations

Applicant's arguments are not found persuasive.

12. Claims 3, 6, 9 and 12 are directed to an invention not patentably distinct from the pending claims of USSNs 08/791,391 and 08/790,540. Specifically, the conflicting claims are patentably distinct from each other because the pending claims are drawn similar or obvious variants of LM609-specific humanized antibodies, fragments and nucleic acids encoding said antibodies/fragments thereof

Commonly assigned USSNs 08/791,391 and 08/790,540., discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. § 103 if the commonly assigned case qualifies as prior art under 35 U.S.C. § 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 37 C.F.R. § 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application. A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. § 103 based upon the commonly assigned case as a reference under 35 U.S.C. § 102(f) or (g).

13. Claims 3, 6, 9 and 12 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending USSNs 08/791,391 and 08/790,540 which have a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future patenting of the conflicting application.

Specifically, the conflicting claims are patentably distinct from each other because the pending claims are drawn similar or obvious variants of LM609-specific humanized antibodies, fragments and nucleic acids encoding said antibodies/fragments thereof

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131.

Applicant's arguments, filed 1/8/02 (Paper No. 18), have been fully considered but are not found convincing essentially for the reasons of record.

Applicant submits that the copending applications do not recite the claimed antibodies, particularly antibodies having a CDR selected from SEQ ID NOS: 104, 106 and 110.

However, given the recitation of "substantially the same sequence"; the prior art humanized LM609 antibodies and fragments thereof claimed in USSNs 08/790,540 and 08/791,3981 would have been expected properties of the prior art LM609-specific antibodies encompassed by the claimed limitations

Applicant's arguments are not found persuasive.

14. Claims 34-45 appear free of the prior art and deemed allowable.

It is noted that the particular recitation of LM609 antibodies comprising the VH CDR1 referenced as SEQ ID NO: 34, the VH CDR2 referenced as SEQ ID NO: 102/104 and the VH CDR3 referenced as SEQ ID NO: 106
as well as the corresponding nucleic acids of
VH CDR1 referenced as SEQ ID NO: 33, the VH CDR2 referenced as SEQ ID NO: 101/105 and the VH CDR3 referenced as SEQ ID NO: 105 appear free of the prior art;
if applicant can distinguish the teachings of Wu et al. (PNAS 95: 6037-6042, 1998; 1449) from the instant claims

15. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

16. Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242 or (703) 305-7939.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1800 receptionist whose telephone number is (703) 308-0196.

Phillip Gambel, Ph.D.
Patent Examiner
Technology Center 1600
April 15, 2002